REMARKS

Claims 1-3 and 15-21 were under examination as of the issuance of the Office Action of April 6, 2005.

Claims 1 and 17 have been amended. Support for the amendments may be found in the specification and claims as originally filed. Specifically, support for claims 1 and 17 can be found, for example, at least on page 5 in the 3rd full paragraph starting with "Asp polypeptides for use..." Accordingly, no new matter has been introduced by these amendments.

The foregoing amendments should in no way be construed as an acquiescence to any of the Examiner's rejections and have been made solely to expedite examination of the present application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s). After entry of these amendments, claims 1-3 and 15-21 will be pending in this application.

Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1-3 and 15-21 have been rejected for failing to comply with the written description requirement. Specifically, the Examiner states:

> ...the transitional phrase 'having' in the claims permits the inclusion of other moieties extending from either the N terminal or C terminal region of the fragment. In addition, the transitional phrase 'having' in relation to the fragment permits sequence, i.e., fragments, outside of the amino acid sequence of SEQ ID NO:1. However, Applicants have not provided evidence to the contrary that they were in possession of the claimed genus of Asp peptide fragments having an amino acid sequence shown in SEQ ID NO:1. For example, while applicants allege that an Asp fragment as being capable of forming and/or maintaining MTOC's or comprises particular regions of the Asp polypeptide (SEQ ID NO:1), applicants fail to mention the structural features which are common to the members of the genus. Secondly, Applicants arguments that the specification provides an assay to determining whether a particular fragment possesses the functional property of forming and/or maintaining MTOC's is not pertinent because the specification only shows the amino acid sequence of SEQ ID NO:1. Therefore, one of skill in the art would not be apprised of what other amino acids could be hanging off of the Asp polypeptide. (Office Action, page 3)

Applicants respectfully disagree. However, in order to expedite examination and in no way acquiescing to the Examiner's rejection, Applicants have amended claim 1 to read on Asp polypeptides *consisting of* the amino acid sequence of SEQ ID NO:1. As the Examiner's

rejection is based on the Applicants' use of the term "having," Applicants submit that the foregoing amendment is sufficient to overcome the Examiner's rejection.

Applicants assert that the amended claims are sufficiently supported by the specification. Initially, Applicants direct the Examiner's attention to MPEP 2163(II)(A)(3)(ii) which states

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568.

Applicants assert that the present application sufficiently characterizes the Asp polypeptide of SEQ ID NO:1 and fragments thereof. Indeed, the specification provides functional characteristics coupled with a known or disclosed correlation between function and structure. In view of the amended claims, Applicants redirect the Examiner's attention to certain sections of the disclosure of the present application. In particular, the claims and the specification characterize a structurally defined Asp polypeptide as being capable of forming and/or maintaining MTOC's (see claim 1 and the last paragraph starting on page 5 and ending on page 6). Moreover, in the third full paragraph of page 6, the specification structurally and functionally defines particular fragments of the Asp polypeptide including, for example, $p34^{cdc2}$ consensus phosphorylation sites, MAP kinase consensus phosphorylation sites, MPM2 epitope phosphorylation sites, putative actin binding sites and IQ motifs. Indeed, as stated in the MPEP, "Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Accordingly, the description of numerous species by the application is sufficient to characterize the genus of fragments as claimed in the present invention.

Moreover, the specification provides assays to determine whether particular fragments not explicitly disclosed by the present application, possess this functional property of forming and/or maintaining MTOC's. For example, on page 20, the specification indicates that the fragments should be capable of recognition by, for example, by binding to, the candidate substances. On pages 22-26, the specification provides Asp binding assays, MTOC nucleation activity assays and whole cell assays to identify the functional properties of the Asp polypeptide fragments and the effect of the candidate substances on such fragments.

Accordingly, Applicants assert that Asp polypeptides consisting of the amino acid sequence of SEQ ID NO: 1 and fragments thereof are sufficiently described in the specification to demonstrate that the Applicants were in possession of the invention as claimed. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-3 and 15-21 have been rejected on the ground that the specification "does not reasonably provide enablement for identifying a substance capable of disrupting microtubule organizing centre (MTOC) integrity by contacting any and/or all fragments thereof having an amino acid sequence of SEQ ID NO:1" (Office Action, page 4).

Initially, the Examiner asserts that

> ...the previous rejection was based on an analysis of whether the disclosure, when filed, supported whether any and/or all fragments having an amino acid sequence of SEQ ID NO:1 can be used for identifying a substance capable of disrupting MTOC integrity, as long as the fragments are capable of forming and/or maintaining MTOC in the absence of the substance as to enable one skilled in the pertinent art to make and use the claimed invention. Applicants have not provided evidence that any/and or all fragments of Asp protein are capable of acting this way. For example, while Applicants allege that the specification describes particular regions that may confer the necessary functional properties of the polypeptide to the fragment and further provides assays for analyzing the function[al] properties of the fragments, Applicants fail to provide examples wherein a Asp polypeptide fragment was capable of functioning as it is claimed. (Office Action, page 4)

Applicants respectfully disagree. Applicants assert that the specification along with the state of the art provide sufficient disclosure to enable one skilled in the art to make fragments of Asp polypeptides in accordance with the present invention. Applicants respectfully submit that one skilled in the art would appreciate that fragments involved in the formation or maintenance of MTOC could be used to design and identify substances to disrupt said function. Furthermore, the specification provides extensive description on how such substances may operate on these fragments so as to disrupt the formation or maintenance of MTOC (see, for example, the first three full paragraphs under "Candidate substances" starting on page 20).

Moreover, the disclosure of the present application in addition to the state of the art provide sufficient disclosure for one skilled in the art to identify whether particular fragments of the Asp

polypeptide of SEQ ID NO:1, whether disclosed or not by the present specification, do in fact possess the requisite functional characteristic of involvement in the formation or maintenance of MTOC. One skilled in the art would be able to identify the functional properties of Asp polypeptide fragments through either standard assays known in the art or through those provided in the specification. Indeed, determining the function of an amino acid sequence is well within the ability of one skilled in the art. Moreover, the specification provides Asp binding assays, MTOC nucleation activity assays and whole cell assays to allow for the production and identification of Asp polypeptide fragments that possess the MTOC integrity functional property which can be affected by the candidate substances of the invention.

In addition, Applicants direct the Examiner's attention to MPEP § 2164.02 which states that "the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation... lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement." Indeed, the present disclosure along with the state of the art renders the scope of the present claims sufficiently enabled so as to render the disclosure of a working example unnecessary.

The Examiner further rejects the pending claims as lacking enablement based on use of term "having." Applicants respectfully disagree. However, in order to expedite examination and in no way acquiescing to the Examiner's rejection, Applicants have amended claim 1 to read on Asp polypeptides *consisting of* the amino acid sequence of SEQ ID NO:1. As the Examiner's rejection is based on the Applicants' use of the term "having," Applicants submit that the foregoing amendment is sufficient to overcome the Examiner's rejection, thereby rendering the pending claims sufficiently enabled.

With regard to Claim 21 specifically, the Examiner argues that "claim 21 is drawn to a genus of Asp polypeptides which are not described in the specification." Applicants assert that the specification, alone or in combination with the state of the art, provides sufficient description to enable one skilled in the art to make the claimed polypeptides. Applicants direct the Examiner's attention to the third full paragraph of page 9, which states, "amino acid substitutions may be made, for example from 1, 2 or 3 to 10, 20 or 30 substitutions provided that the modified sequence retains activity in maintaining microtubule organising centre integrity,

preferably at least 50% of the activity of the Asp polypeptide shown in SEQ I.D. No. 1, more preferably at least the same activity." It would have been well within the ability of one skilled in the art at the time of filing of the present application to make a fragment of an Asp polypeptide with certain substitutions and to test the resulting fragment to confirm that it has retained the requisite functional property. In addition, as stated earlier, the specification provides Asp binding assays, MTOC nucleation activity assays and whole cell assays to allow for the production and identification of Asp polypeptide fragments that possess the MTOC integrity functional property which can be affected by the candidate substances of the invention.

Accordingly, Applicants assert that the specification sufficiently enables one skilled in the art to make, use and identify Asp polypeptide fragments possessing the required functional property of the pending claims, and respectfully request reconsideration and withdrawal of this rejection of claims 1-3 and 15-21 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested. If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

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Respectfully submitted,

By _____

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